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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,244	04/02/2001	Sharat Singh	0225-0033.24	2665

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EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 03/28/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/825,244

Applicant(s)

Singh et al.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1637.

Specification

1. Claims 8-10 are objected to because of the following informalities: it appears that there are discussion notes in the claims. Appropriate correction is required.

Double Patenting

2. Claims 1-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No.09/824984 and claims 1-10 of copending Application No. 09/825,247. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 1-20 are drawn to a set of e-tag probes which has the same features as the e-tag reporter used in the method claims 1-4 of copending Application No.09/824984 and claims 1-10 of copending Application No. 09/825,247. Thus it would have been motivated to an ordinary skill in the art to claim a set of e-tag probe because the same e-tag probe is used in the method of the copending application.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 1-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 09/825,245, claims 1-15 of copending Application No. 09/825, 246, claims 1-10 of copending Application No 09/824,905, claims 1-4 of copending Application No. 09/824,861 and claims 1-4 of copending Application No. 09/824,851. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 1-20 are drawn to a set of e-tag probes which has the same features as the e-tag probe in the kit or composition in the copending application as listed above. It would have been prima facies obvious to claim a set of e-tag probe in instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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a. Claim 10 is vague and indefinite because the language "substrate" has no antecedent basis from claim 1 where the language is referred. It is unclear what is different between the fixed moiety L of the substrate and the moiety L of the e-tag probe. Further, it is unclear what is a substrate probe

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-2, 8, and 11-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Grossman et al. (5,470,705).

Grossman et al. disclose a probe comprising the feature of the e-tag probe as claimed in claim 1 and its dependent claims 2, 8 and 11-20. The probe of Grossman et al. is captured (See column 20, lines 47-49). This is inherent that there is a capture agent bound to the probe. The probe includes a binding polymer, a polymer chain which imparts to that probe, a distinctive ratio of charge/translational frictional drag and a reporter attached to the binding polymer (See column 20, lines 52-57). The probe is also cleavable with nuclease at the 5' end subunits from the probe and the probe releases a labeled probe composed of base, reporter and polymer chain (See column 19, lines 62-67 to column 20, lines 1-25). The binding polymer is an oligonucleotide

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including at least 10-20 bases allowing hybridization to the target polynucleotide (See column 6, lines 66-67 and column 7, lines 1-10). Other binding polymers are analogs of polynucleotide, such as deoxynucleotides with thiophosphodiester linkage (See column 7, lines 11-19). The polymer chain has a ratio of charge/translational frictional drag which is evidenced by a distinctive electrophoretic mobility in a non-sieving matrix (See column 7, lines 50-64). The oligonucleotide binding polymer is derivatized, at its 5' end with a polymer chain and the polymer chains are formed of polypeptide and oligosaccharide, polyethylene oxide (See column 7, lines 39-49). These teachings are inherent that the limitations of claims 15-16 are taught. The label refers to a fluorophore or chromophore (See column 6, lines 39-44). The features of Grossman et al.'s probe anticipate the features of the claimed e-tag probe.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grossman et al. (5,470,705) as applied to claims 1-2, 8, and 11-20 above, and further in view of McGall (5,843,655).

The teachings of Grossman et al. are set forth in section 7 above and Grossman et al. do not indicate that ester linkage is cleaved by esterase and a disulfide bond is cleaved by oxidase enzyme.

McGall disclose that a disulfide linkage is cleaved by reducing condition, ester linkage is cleaved under basic or nucleophilic conditions (See column 8, lines 16-21) and the released nucleic acid products carry the detectable label (See column 8, lines 16-31).

It would have been prima facie obvious to apply a disulfide bond and ester linkage to the probe of Grossman et al. as taught by McGall because McGall discloses that the method is for detecting the presence of cleavable structural feature, such as double stranded nucleic acid with these linkages (See the Abstract) and this teaching suggests that cleavage is efficient. Thus, an ordinary skill in the art would have combined the references to carry out the method as claimed.

10. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grossman et al. (5,470,705) as applied to claims 1-2, 8, and 11-20 above, and further in view of Breslow et al. (6,331,530).

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The teachings of Grossman et al. are set forth in section 7 above and Grossman et al. do not indicate the linkage is cleaved by singlet oxygen.

Breslow et al. disclose a linker used in the system for cancer therapy which is cleaved by singlet oxygen (See column 3, lines 47-51 and column 4, lines 42-45).

It have been prima facie obvious to an ordinary skill in the art at the time of instant invention to conjugate the active cleaving agent, singlet oxygen as taught by Breslow et al. to the probe of Grossman et al. because the active cleaving agent, singlet oxygen is used in the system for cancer therapy and this suggests that the active cleaving agent must be very efficient. Thus, an ordinary skill in the art would have combined the teachings of the references to carry out instant invention.

11 Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grossman et al. (5,470,705) as applied to claims 1-2, 8 and 11-20 above, and further in view of Cantor et al. (5,849,878).

The teachings of Grossman et al. are set forth in section 7 above and Grossman et al. do not indicate that the ligands are represented by T_j and are members of a combinatorial library of small organic molecules and antiligand is the receptor.

Cantor et al. disclose bis-protein-DNA conjugates, the protein has a specific ligand binding activity covalently linked to each end of a derivatized DNA molecule and the DNA can contain one or more restriction enzyme sites (See column 3, lines 11-27). This suggests that the DNA is cleavable. Cantor et al. also indicate that T cell receptors may be triggered via certain

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anti-receptor monoclonal antibodies (See column 2, lines 23-37). This suggests the limitations of claim 9. The conjugates can be used to study the relationship between cell surface proteins (See column 3, lines 19-27).

It would have been prima facie obvious to an ordinary skill in the art at the time of instant invention to modify the probe of Grossman et al. by conjugating an antibody on an oligonucleotide for screening a ligand capable of binding to a receptor on cell as taught by Cantor et al. because Cantor et al. disclose the method of making the protein-DNA conjugates (See the entire document), the receptor has monoclonal antibody as indicated by Cantor et al. (5,849,878) and the conjugates can be used to study the relationship between cell surface proteins (See column 3, lines 19-27). Thus, an ordinary skill in the art would have applied the teachings of Cantor et al. to make instant invention.

12. The drawings are proved.

13. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

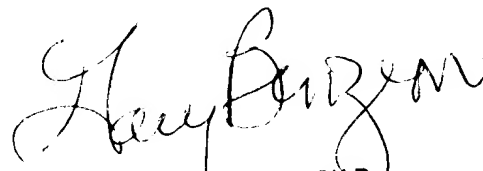
Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

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14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1656 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

March 19, 2002


GARY BENZION, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600